UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: State of Montana v. Abbott Labs., Inc., et al., 02-CV-12084-PBS State of Nevada v. American Home Products Corp., et al., 02-CV-12086-PBS County of Suffolk v. Abbott Laboratories, Inc., et al., 01-CV-12257-PBS	

BRIEF OF THE UNITED STATES AS AMICUS CURIAE

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STATEMENT

The United States Department of Justice, on behalf of the Secretary of Health and Human Services (Secretary), submits this *amicus curiae* brief in response to the Court's request that the Secretary address two issues arising from the above-referenced litigation: first, whether the Medicaid drug rebate statute, 42 U.S.C. § 1396r-8, preempts state law fraud claims based on fraudulent reporting of best prices to the federal government; second, whether the federal government has the authority to bring suit to recover amounts allegedly owed to the states because of the fraudulent reporting of best prices to the federal government. See Letter from Judge Patti B. Saris to Secretary Tommy G. Thompson (Jan. 8, 2004).

On the first question, we do not believe that the Medicaid rebate statute demands the preemption of Montana or Nevada's best price claims as a matter of law. As currently pled, the states' best price claims neither frustrate the administration of the rebate program nor raise the same sort of concerns at issue in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001). Given the above, we do not believe it necessary to reach the second question. This is particularly so given the strong likelihood that the United States would invite the states to join as co-plaintiffs in any federal lawsuit alleging violations of the Medicaid rebate statute or agreement. In the event the situation did arise, however, the United States retains the authority to enforce the rebate statute and agreement and to compel a drug manufacturer to comply fully with its rebate obligations and to make any payments necessitated by such compliance.

BACKGROUND

The Medicaid program, established by Title XIX of the Social Security Act, is a cooperative federal-state program that provides medical assistance to certain low income individuals. See 42 U.S.C. 1396 *et seq.* Under the Medicaid program, "[t]he federal government

sets certain broad standards . . . and provides funds to states that elect to participate." Montana v. Abbott Labs., 266 F.Supp.2d 250, 253 (D. Mass. 2003). "Each participating state determines, within the federal guidelines, its own rules for program eligibility and content of medical care; each state then administers its program, and complements the federal funding with state appropriations." Id. The Centers for Medicare & Medicaid Services (CMS)(formerly the Health Care Financing Administration) administers the Medicaid program on behalf of the Secretary. 42 U.S.C. § 1396a (1994 & Supp. V 1999).

States are accorded a broad measure of flexibility in tailoring the scope and coverage of their state plans to meet the particular needs of their residents and their own budgetary and other circumstances. See Alexander v. Choate, 469 U.S. 287, 303 (1985). Although the Medicaid Act does not require states to cover prescription drugs, 42 U.S.C. § 1396d(a)(12), at least 44 states and the District of Columbia currently provide prescription drug coverage for categorically needy individuals, and 32 states and the District of Columbia provide such coverage for medically needy individuals. See R. Schwalberg, Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey and Selected Case Study Highlights 4 (Oct. 2001). Drugs purchased by Medicaid recipients account for roughly 10% of all prescription drugs purchased in the United States. See Staff of House Comm. on Ways & Means, 106th Cong., 2d Sess. 2000 Green Book 927 (Comm. Print 2000) (Green Book); see also id. at 924 (Table 15-21).

In 1990, Congress reviewed the prices that Medicaid was paying for prescription drugs. Congress determined that Medicaid was routinely paying more for prescription drugs than other large drug purchasers, particularly with respect to single source drugs. See H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). Congress concluded that "Medicaid, the means-tested

entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy." Id. Congress therefore decided to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." Id.

Congress passed the Medicaid drug rebate statute as part of the Omnibus Budget Reconciliation Act of 1990. 42 U.S.C. § 1396r-8. Under that statute, a drug manufacturer must enter into a rebate agreement with the Secretary[1] in order for federal matching funds to be made available for that manufacturer's covered outpatient drugs. 42 U.S.C. § 1396r-8(a)(1); Rebate Agreement at §II(a). Upon entering a rebate agreement with the Secretary, the manufacturer must pay a quarterly rebate directly to each state based on all of the manufacturer's drugs purchased by that state pursuant to its state Medicaid plan during that quarter.[2] 42 U.S.C. § 1396r-8(b)(1)(A); Rebate Agreement at § II(a). Each state must agree to cover all the manufacturer's covered outpatient drugs unless the state complies with one of several statutory provisions allowing it to exclude or restrict coverage. 42 U.S.C. §§ 1396a(a)(54), 1396r-8(d)). The federal share of any rebate amounts received under the national rebate agreement or an

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[1] The rebate agreement provides that the Secretary enters the agreement "on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent they have in force an Individual State Agreement)." See Rebate Agreement at Preamble.

[2] For single source or innovator multiple source drugs, the rebate due on each unit paid for under the state plan is the difference between the average manufacturer price (AMP) and the manufacturer's best price, defined as the lowest price available from the manufacturer to any private purchaser or governmental entity within the United States, or 15.1% of AMP, whichever is greater. 42 U.S.C. § 1396r-8(c)(1)(A), (B), and (C) and (c)(2). For multiple source non-innovator drugs, the rebate is 11% of average manufacturer price. 42 U.S.C. § 1396r-8(c)(3).

individual state rebate agreement must be offset against the state's Medicaid expenditures that quarter for purposes of calculating the federal financial participation.[3] 42 U.S.C. § 1396r-8(b)(1)(B).

States may enter directly into rebate agreements with drug manufacturers as authorized by the Secretary. 42 U.S.C. § 1396r-8(a)(1). To date, the Secretary has approved supplemental drug rebate agreements in at least twenty states. States may also control their Medicaid drug costs and coverage by establishing prior authorization programs, 42 U.S.C. § 1396r-8(d)(1)(A), or by creating drug formularies, 42 U.S.C. 1396r-8(d)(1)(B)(iv). Though not part of the rebate statute, states are also permitted to set payment rates with respect to covered drugs. See 42 U.S.C. 1396a(a)(30); 42 C.F.R. 447.331-447.333.

Drug manufacturers are required under the rebate statute and agreement to calculate and report their AMPs and best prices to the Secretary on a quarterly basis. 42 U.S.C. § 1396r-8(b)(3)(A)(i); Rebate Agreement at § II(e). Any information provided by a manufacturer or wholesaler under the rebate statute is confidential and "shall not be disclosed by the Secretary . . . or a State agency . . . except as the Secretary determines to be necessary to carry out this section." 42 U.S.C. § 1396r-8(b)(3)(D); Rebate Agreement at § VII. States are required to report their total Medicaid drug utilization to each manufacturer and the Secretary sixty days after the end of each rebate quarter.[4] 42 U.S.C. § 1396r-8(b)(2)(A). Using the manufacturer

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[3] The federal share is equal to a percentage (between 50% and 83% depending on the state) of the state's Medicaid expenditures.

[4] The rebate agreement provides a dispute resolution mechanism in the event there is a discrepancy between a state and manufacturer regarding the state's Medicaid utilization information. Rebate Agreement at § V.

pricing data, CMS computes the unit rebate amount (URA) "to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due." Rebate Agreement at § I(dd).

The Secretary may survey wholesalers and manufacturers to verify reported AMPs and best prices, 42 U.S.C. § 1396r-8(b)(3)(B), and may audit manufacturer calculations of AMP and best price. Rebate Agreement at § III(c). The Secretary may impose civil money penalties on manufacturers that either fail to timely report their pricing information or submit false information to the Secretary. 42 U.S.C. § 1396r-8(b)(3)(C); Rebate Agreement at §§ III, IV. Section 1396r-8(b)(3)(C)(ii) also provides that any civil money penalties imposed under this subsection are "in addition to other penalties as may be prescribed by law." The Secretary may terminate the rebate agreement for either violations of the rebate agreement or for other good cause shown. 42 U.S.C. § 1396r-8(b)(4)(B). The rebate agreement is construed in accordance with federal common law and any "ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." Rebate Agreement at IX(e).

In addition to the rebate statute and agreement, CMS has provided manufacturers with supplemental guidance regarding their best price responsibilities. First, CMS has published, as necessary, a series of Medicaid drug rebate program releases. These program releases clarify program requirements and respond to questions raised by manufacturers or states. See www.cms.hhs.gov/medicaid/drugs/drughmpg.asp. Second, CMS offers a "Medicaid Drug Rebate Operational Training Guide" to all participating manufacturers. The training guide serves as a reference source on technical issues such as data formatting and calculation methodologies. Finally, the Federal Register Notice of Proposed Rulemaking contains some of

the Secretary's interpretations of manufacturer best price reporting obligations. See Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Manufacturers, 60 Fed. Reg. 48442 (Sept. 19, 1995), see also, Medicaid Program; Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program, 69 Fed. Reg. 508 (Jan. 6, 2004).

DISCUSSION

I. Montana and Nevada's State Law Best Price Claims Are Not Inconsistent With The Objectives Of The Medicaid Rebate Statute

Under the Supremacy Clause, a federal law may preempt state law either expressly or impliedly. U.S. Const. art. VI, cl. 2; see Gade v. National Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992); English v. General Elec. Co., 496 U.S. 72, 78-79 (1990). In this case, the rebate statute is silent as to the availability of state law actions alleging best price violations. Therefore, the only question remaining is whether implied preemption applies. The Supreme Court has held that implied conflict preemption may arise where "compliance with both federal and state regulations is a physical impossibility," Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-43 (1963), or, where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1941).[5]

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[5] The Supreme Court has also held that state law may be impliedly preempted where the federal regulatory scheme is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230 (1947). Given that Medicaid is a cooperative federal-state program, that states play a significant role in defining their own state Medicaid plans, and that Congress has not expressed a clear and manifest intent to preempt the entire field of Medicaid drug reimbursement, the doctrine of field preemption is not applicable here. See also PhRMA v. Concannon, 249 F.3d 66, 75 (1st Cir. 2001); PhRMA v. Meadows, 304 F.3d 1197, 1206 (11th Cir. 2002).

Regardless of the particular strain of preemption, congressional intent is generally the touchstone of a preemption analysis. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996); Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992). Moreover, courts that perform preemption analyses should "start with the assumption that the historic police powers of the States were not to be superceded by [a] Federal Act unless that was the clear and manifest purpose of Congress." Rice, 331 U.S. at 230; see Medtronic, 518 U.S. at 485 ("[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state law causes of action."); Mass. Ass'n of Health Maintenance Orgs. v. Ruthardt, 194 F.3d 176, 178-179 (1st Cir. 1999) ("[A]lthough the power to preempt is absolute, its exercise is not lightly to be presumed."); Greenwood Trust Co. v. Commonwealth of Massachusetts, 971 F.2d 818, 823 (1st Cir. 1992) ("Courts must tread cautiously in this arena because the authority to displace a sovereign state's law is an extraordinary power . . . that we must assume Congress does not exercise lightly.") (internal quotation omitted). Particularly "[w]here coordinate state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal pre-emption becomes a less persuasive one." N.Y. Dep't of Soc. Servs. v. Dublino, 413 U.S. 405, 421 (1973).

As a unique "system of cooperative federalism," Harris v. McRae, 448 U.S. 297, 301 (1980), the Medicaid program falls squarely within this field where courts must tread cautiously before displacing state law. Indeed, as the Supreme Court recently noted in a case challenging a state prior authorization program under the Medicaid rebate statute, "[t]he presumption against federal pre-emption of a state statute designed to foster public health . . . has special force when it appears, and the Secretary has not decided to the contrary, that the two governments are

pursuing common purposes." PhRMA v. Walsh, 123 S.Ct. 1855, 1869 (2003).[6] See also Meadows, 304 F.3d at 1206 ("Medicaid is one of several cooperative state-federal program[s] covered by the Social Security Act, and the Supreme Court has suggested that preemption for these types of programs may be difficult to establish."), cert. denied, 123 S.Ct. 2213 (2003); Concannon, 249 F.3d at 75("We also recognize that federal preemption of state law is strong medicine, and is not casually to be dispensed . . . especially . . . when the federal statute creates a program, such as Medicaid, that utilizes cooperative federalism.") (internal quotations omitted); PhRMA v. Thompson, 259 F.Supp.2d 39, 84 (D.D.C. 2003), appeal docketed, No. 03-5117 (D.C. Cir. Dec. 12, 2003); Cf. In re. Pharmaceutical Industry Average Wholesale Price Litigation, 263 F.Supp.2d 172, 187 (D. Mass. 2003)(finding that the Medicare Act did not preempt the entire field of medical fee regulation).

Against this backdrop, there is no persuasive reason why the presumption against preempting state law in the Medicaid context should not be applied to Montana and Nevada's best price claims. States obviously have a direct and compelling interest in accurate best price reporting and the rebate program, which helps to reduce the costs the states themselves incurred for drugs purchased by Medicaid patients. Furthermore, states have long played a critical role in investigating and prosecuting Medicaid fraud. See 42 U.S.C. § 1396b(q)(3) (requiring states to maintain a Medicaid Fraud Control Unit (MFCU) to investigate fraud in connection with Medicaid State plan); 42 U.S.C. § 1396a(a)(61) (requiring state plan to provide for operation of a Medicaid fraud and abuse control unit); 42 U.S.C. § 1396a(a)(25) (requiring states to "take all

[6] The Pharmaceutical Research and Manufacturers of America will be hereinafter referred to as "PhRMA."

reasonable measures to ascertain the legal liability of third parties" and to pursue reimbursement.[7] Finally, to the extent that states identify and prosecute a manufacturer that violates its best price reporting obligations as alleged in this case, such actions would presumably advance, not hinder, the congressional objectives of reducing Medicaid drug costs and ensuring that state Medicaid programs are given the full benefit obtained by other high volume purchasers of prescription drugs. See PhRMA v. Thompson, 235 F.3d 219, 225 (D.C. Cir. 2001) (noting that Congress imposed the rebate requirement to reduce the costs of Medicaid and to prevent pharmaceutical manufacturers from charging the government and taxpayers above-market prices for Medicaid drugs). Given that Montana and Nevada are, in this instance, "pursuing common purposes" with the federal government through their best price claims, see Walsh, 123 S.Ct. at 1869, Dublino, 413 U.S. at 421, the case for preemption is particularly weak.

A. Allowing Montana And Nevada To Pursue State Law Best Price Claims Does Not Create A "Phyisical Impossibility" For The Defendants

As discussed above, federal law may impliedly preempt state law where "compliance with both federal and state regulations is a physical impossibility." Florida Lime, 373 U.S. at 142-43. An example of such a "physical impossibility" arose in Boyle v. United Technologies Corp., 487 U.S. 500 (1988), where the state-imposed duty of care asserted by the private plaintiffs (to equip helicopters with an escape hatch door that opened inwards) was precisely

[7] The statutory charge of MFCUs is broader than suggested by the Defendants. Pursuant to 42 U.S.C. §1396b(q)(3), MFCUs are charged with investigating and prosecuting "violations of all applicable State laws regarding any and all aspects of fraud in connection with . . . any aspect of the provision of medical assistance and the activities of providers of such assistance under the State plan under this subchapter[.]" Given the direct impact that best price fraud has on a state's Medicaid funding, and consequently its ability to provide assistance to beneficiaries, it is within their statutory authority to investigate and prosecute Medicaid best price violations as alleged in this case.

contrary to the duty imposed by the federal government contract (to manufacture and deliver helicopters with an escape-hatch mechanism that opened outwards). 487 U.S. at 509.

At least based on the present record, the Defendants have not identified any state-imposed obligation that directly conflicts with their best price obligations as defined in the rebate statute or agreement. Neither Montana nor Nevada is asking, for example, the Defendants to include nominal prices, or exclude cash discounts, in their best price calculations in conflict with 42 U.S.C. §1396r-8(c)(1)(C)(ii)(I) & (II). Instead, these states' best price allegations, at least as currently pled, merely require the Defendants to properly account for all relevant discounts (i.e., free goods, volume discounts, educational grants, discounts to HMO's) that may have effectively lowered their best prices. Requiring the Defendants to comply with their already existing statutory and rebate agreement obligations hardly creates an actual conflict, much less a "physical impossibility," that would warrant preemption. Cf. Boyle, 487 U.S. 508-509 (observing how private plaintiffs in Miree v. DeKalb County, 433 U.S. 25 (1977), were "not seeking to impose upon the person contracting with the Government a duty contrary to the duty imposed by the Government contract . . . [but] [r]ather, it was the contractual duty *itself* that the private plaintiff (as third-party beneficiary) sought to enforce.") (emphasis in original).[8]

Thus, because Montana and Nevada's state law best price allegations do not require the Defendants to do anything different from (much less contrary to) their obligations under the

[8] In Miree, survivors of deceased aircraft passengers filed state law claims against the county where the aircraft crashed. 433 U.S. at 25-6. In addition to negligence and nuisance claims, the private plaintiffs alleged that the county had breached its grant contract with the Federal Aviation Administration by failing to restrict the use of land adjacent to the airport. Id. at 25. The plaintiffs alleged that the county breached the contract by operating a garbage dump near the airport and that the crash was caused by the ingestion of birds swarming from the dump into the aircraft's jet engine shortly after takeoff. Id.

rebate statute and agreement, it is not "physically impossible" for the Defendants to comply with both federal and state law and therefore no basis for implied conflict preemption exists.

B. Nevada and Montana's State Law Best Price Claims Do Not Present An Obstacle To Or Impose A Buckman-Type Burden On The Medicaid Rebate Program

In the absence of a "physical impossibility", the Defendants argue that the Medicaid rebate statute impliedly preempts the States' best price claims by frustrating the Medicaid rebate program. Relying upon Buckman, the Defendants argue that the rebate statute and program recommend exclusive federal enforcement of best price violations and that the state law best price claims would only burden the rebate program. A more in-depth factual comparison of the regulatory schemes, however, reveals significant differences that render Buckman inapplicable here.

In Buckman, the Court held that the state law "fraud on the FDA" claims alleged conflicted with, and were therefore impliedly preempted by, the Food, Drug, and Cosmetic Act (FDCA), as amended by the Medical Device Amendments (MDA) of 1976. 531 U.S. at 353. The Court based its ruling on several factors. First, the Court held that the traditional presumption against preemption of state law did not apply given that "[p]olicing fraud against federal agencies [was] hardly a field which the States have traditionally occupied," id. at 347-48 (internal quotation omitted), and that the relationship between a federal agency and the entities it regulates was "inherently federal in character." Id. at 347. Second, the Court held that the extensive federal statutory scheme amply empowered the FDA to punish and deter fraud against the Administration. Id. at 348-49. Finally, the Court held that the state law "fraud-on-the-FDA" would inevitably disrupt the FDA's ability to achieve its statutory objectives. Id. at 348. We address each of these factors in turn.

1. The Presumption Against Preempting State Law In the Medicaid Context Applies In This Case

At the outset, the presumption against preempting state law applies in this case. As discussed above, the best price claims here arise in the Medicaid context, where state and federal governments generally work in a complementary administrative framework and pursue common purposes. See Walsh, 123 S.Ct. at 1869; Dublino, 413 U.S. at 421; Meadows, 304 F.3d at 1206; Concannon, 249 F.3d at 75. That the best price claims here are brought by states-- which have historically played a significant role in investigating and prosecuting Medicaid fraud--further weakens the case for preemption.

Buckman does not materially change this analysis. First, in contrast to the "inherently federal" relationship between the FDA and the entities it regulates, see Buckman, 531 U.S. at 347, the states and the federal government share a compelling interest in manufacturers accurately calculating and reporting their best prices. Indeed, given that the states suffer directly from every false or fraudulent best price reported, their claims cannot be fairly characterized as merely "fraud-on-the-agency." Second, in contrast to the private plaintiffs in Buckman, states have played a historical role in the investigation and prosecution of Medicaid fraud, see supra at 9, and therefore the state law best price claims at issue in this case directly implicate "federalism concerns" and state responsibilities. Id. at 347-48. Moreover, the states' best price claims may help fulfill Congress's objective of reducing state Medicaid drug costs and thereby better enable states to provide health care services to their poorest citizens. Cf. Meadows, 304 F.3d at 1197 ("By stretching its Medicaid dollars, the Florida [prior authorization program] has the potential for providing more and better medical services to the target population."). Against this backdrop, the fact that the manufacturers' reporting obligations are defined by the rebate statute

and agreement does not automatically negate the states' interest in accurate best price reporting or transform the federal government's interest into a "uniquely federal" one.[9] Boyle, 487 U.S. at 504-505.

For these reasons, we find no persuasive reason to disregard the states' interest in the rebate program altogether or to isolate the states' best price claims from the presumption against preemption that otherwise prevails in the Medicaid context.

2. The Statutory Scheme Does Not Demand Exclusive Federal Enforcement Of The Medicaid Rebate Program

In Buckman, the Court found that the statutory and regulatory scheme at issue provided the FDA with a "variety of enforcement options that allow[ed] it to make a measured response to suspected fraud upon the Administration." Id. at 349. Based in part on that regulatory scheme, the Court inferred that there was no room for State action in this arena. The Medicaid drug rebate scheme does not warrant a similar inference.

First, unlike the FDCA or MDA, the rebate statute does not contain any provision akin to 21 U.S.C. § 337(a) ("[A]ll such [medical device noncompliance] proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States"), that would suggest a Congressional desire for exclusive federal enforcement. Given the historical role that states play in investigating and prosecuting Medicaid fraud, the direct interest

[9] In Boyle, the Court held that despite the absence of any federal legislation immunizing independent contractors, federal common law should nevertheless govern their liability given the "uniquely federal interest" that the federal government had in its procurement contracts. Id. at 504-507. In this case, there is no dispute that the rebate agreement should be construed in accordance with federal common law or that the federal government has an interest in any litigation involving the rebate program. We do not believe, however, that the federal government's interest in the Defendants' best price reporting is somehow so "uniquely" federal as to warrant preemption in this case.

that states have in the rebate program, and the flexibility that the rebate statute otherwise accords states to control their Medicaid drug costs, it is not unreasonable to expect Congress to have expressly provided for *exclusive* federal enforcement if that were indeed its intent.

Second, while the drug rebate scheme is well-suited for gathering pricing data and administering the quarterly drug rebates, it is not specifically designed for identifying fraud. Although the Secretary has the authority to survey wholesaler and manufacturer AMPs and best prices, 42 U.S.C. § 1396r-8(b)(3)(B), and to assess penalties for late or false information provided, id. at section 1396r-8(b)(3)(C), neither the rebate statute nor rebate agreement provides for the periodic or systematic review of manufacturer best price calculations or methodologies. Therefore, unlike the FDA regulatory scheme which requires applicants to provide detailed information regarding their devices for agency review, see Buckman, 531 U.S. at 348-49, the rebate program does not require manufacturers to submit invoices to support their best price calculations or to regularly explain their methodologies for calculating AMP or best price. Without requiring manufacturers to regularly provide the invoices, data or methodologies underlying their best prices, it is unreasonable to infer that the Secretary should bear the sole responsibility for monitoring best price fraud.

Finally, the Medicaid statute's confidentiality provision does not provide a sufficient basis to infer congressional intent to bar state enforcement actions. Section 1396r-8(b)(3)(D) provides that:

> Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph . . . is confidential and shall not be disclosed by the Secretary . . . or a State agency . . . in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except–
> (i) as the Secretary determines to be necessary to carry out [Section 1927.]

In order to preserve the confidentiality of manufacturer pricing data, while allowing states to verify the accuracy of their quarterly rebates, the Secretary provides the states with the URAs, and not the AMPs or best prices. See Medicaid Program: Payment for Covered Outpatient Drugs Under Drug Rebate Agreements With Manufacturers, 60 Fed. Reg. 48442, *48475 (Sept. 19, 1995). The Secretary struck this particular balance for purposes of the ordinary administration of the rebate program in compliance with the statute. 42 U.S.C. § 1396r-8(b)(3)(D)(i)(concerning disclosure "as the Secretary determines necessary to carry out this section."). This balance does not preclude states from obtaining such data from other sources (such as Defendants). Likewise, while the confidentiality provision should encourage states to coordinate with the CMS before filing best price claims, it does not provide an adequate basis to infer Congress's desire for *exclusive* federal rebate enforcement, especially given the historical role of state MFCUs in investigating and prosecuting Medicaid fraud.

For all the above reasons, we do not believe the structure of the rebate program supports the inference that Congress intended for only the federal government or CMS to pursue Medicaid best price fraud.

3. Nevada and Montana's State Law Claims Will Not Obstruct The Secretary's Ability To Administer The Rebate Program Or To Achieve Congressional Objectives

In Buckman, the Court was persuaded that the state law "fraud on the agency" claims would put an "extraneous pull" on the FDA statutory and regulatory scheme and distort the FDA's "delicate balance of statutory objectives." 531 U.S. at 348, 353. By having to comply with the FDA's regulatory regime and fifty state tort regimes, potential applicants could be both deterred from seeking FDA approval or encouraged to submit too much information to the FDA

to avoid potential state court liability later. Id. at 350-51. The Court believed that these and other unforeseen consequences were unintended by Congress and "inevitably conflict[ed] with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." Id. at 350. Again, the concerns at issue in Buckman are less an issue in this context.

First, unlike in Buckman, the best price allegations in this case would not necessarily conflict with or otherwise distort a federal agency determination. As discussed above, CMS computes the quarterly URAs using the manufacturer reported AMPs and best prices. Although the volume of data is massive, the calculations are performed electronically by CMS's Medicaid Drug Rebate Initiative System based on formulae primarily established by the rebate statute and Agreement. See Training Guide, at § H2-H16. If the states in this case successfully prove that the Defendants' best price calculations failed to include these discounts, CMS could request manufacturers to perform a recalculation.

Buckman would be much more germane were CMS responsible for and actively engaged in negotiating with manufacturers for the drug prices. In that situation, state law fraud claims alleging best price violations could conceivably distort a substantive decision made by the agency on the proper reimbursement rate for a particular product. Here, to the extent that a state successfully identifies and prosecutes a best price violation, such as alleged in this case by Montana and Nevada, such an action would not be second-guessing any agency determination and would instead be advancing Congress's objective of reducing Medicaid drug costs.

Second, the Defendants have failed to demonstrate how state law best price claims would affect their behavior in a manner that conflicts with or facially impacts the rebate program. In Buckman, the Court identified specific ways that the "fraud on the agency" claims would likely

impact an applicant's behavior to the detriment of the FDA approval process. 531 U.S. 350-52. In this case, while referring to the "insuperable compliance obstacles" and "dramatically increas[ed] burdens" that would result from state regulation in this arena, see Consolidated Memorandum in Support of the Defendants' Motion To Dismiss the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint, at 9, the only concrete example articulated is having to file a state specific quarterly report instead of a single uniform report to CMS. Id. at 9-10. This is hardly enough, if relevant at all, given that the net result is to "produce savings for the Medicaid program." Walsh, 123 S.Ct. at 1870. Manufacturers participating in the rebate program already contend with some state rebate variation with regard to prior authorization programs, formularies, or supplemental rebate agreements. Against this backdrop, we are not persuaded that requiring manufacturers to report state-specific best prices to CMS– after a court has found that manufacturer to have fraudulently miscalculated or misreported its best price– would be so burdensome as to fatally disrupt the rebate program.

Third, the Defendants overstate the likelihood of a "patchwork of liability." As this Court previously noted, "state courts frequently construe terms in federal laws in order to adjudicate causes of action based in state law" and the Supreme Court is the "ultimate decision-maker on federal questions arising out of state court." Abbott, 266 F.Supp.2d at 253. To the extent that a state sues a drug manufacturer that failed to calculate its best price obligations in accordance with the rebate agreement or CMS guidance-- but does not seek to impose any additional or contrary obligations– the state is merely enforcing the existing rebate program responsibilities and does not inject any more variation than if the Department of Justice brought suit. Moreover, to the extent a state alleges a best price violation (like Nevada or Montana)

based on a type of transaction already addressed by CMS, agency guidance will naturally limit the amount of state, or federal, court variation. Given the Secretary's significant expertise in administering the Medicaid program, see Walsh, 123 S.Ct. at 1872; Wisconsin Dep't of Health & Family Servs. v. Blumer, 534 U.S. 473, 479 (2002) (Secretary's interpretations of Medicaid statute "warrants respectful consideration"), any guidance or interpretation provided by the agency regarding the Medicaid drug rebate provisions will be entitled to deference by courts and states when bringing such actions.[10] See Thompson, 259 F.Supp.2d at 69-71. Finally, while "the need for uniformity in enforcement is an important goal which should be considered in determining preemption," Abbott, 263 F.Supp.2d at 188, it is not so heavy a concern in this case as to outweigh both the States' direct financial interest in accurate best price reporting or Congress's objective of reducing Medicaid drug costs.

For the reasons discussed above, we do not believe that the Defendants have adequately demonstrated that the state law best price claims in this case will impose such a burden on the Medicaid drug rebate program as to warrant their wholesale preemption. While time may prove otherwise, the burdens and obstacles claimed by the Defendants are simply too speculative and remote to justify preempting all state law best price claims at this stage of the proceeding.

[10] If, upon reviewing a particular sales transaction or type of transaction CMS concludes that a price should be included or excluded with respect to best price calculations, then such a determination would be dispositive and preclude state court action to the contrary.

II. The Federal Government Has The Authority To Enforce the Medicaid Rebate Agreements Between Manufacturers And The Secretary

Given the discussion above, we do not believe it is critical to address whether the United States has the authority to bring suit to recover amounts allegedly owed to the states due to the fraudulent reporting of best prices. Indeed, as a practical matter, we believe this situation is unlikely to materialize because the United States would likely invite the states to join as co-plaintiffs in any federal action filed against a manufacturer for alleged violations of the Medicaid rebate statute or rebate agreement.[11]

Assuming this situation arose, however, the United States has the authority to enforce the obligations set forth in the Medicaid rebate statute, 42 U.S.C. § 1396r-8, and the rebate agreement. The Secretary is already expressly empowered to survey wholesalers and manufacturers to verify reported AMPs and best prices, 42 U.S.C. § 1396r-8(b)(3)(B), to impose civil money penalties for the false or untimely submission of best prices, 42 U.S.C. § 1396r-8(b)(3)(C); Rebate Agreement at §§ III, IV, and to terminate the rebate agreement for violations or for other good cause shown, 42 U.S.C. § 1396r-8(b)(4)(B); Rebate Agreement at § VIII(c). Moreover, the Agreement expressly provides that "[n]othing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other federal laws, or state laws." Rebate Agreement at § IX(d).

The United States retains the right to enforce the provisions of the Medicaid rebate statute and rebate agreement by suing a drug manufacturer for an alleged best price violation

[11] In a False Claims Act action pursuant to 31 U.S.C. § 3730, the district courts have jurisdiction over state law claims that arise from the same transaction or occurrence as the action under section 3730. 31 U.S.C. § 3732(b).

pursuant to 28 U.S.C. §§ 1331, 1345, and to compel the manufacturer to fully comply with the rebate obligations it assumed under the rebate agreement. For example, if a manufacturer failed to include a particular discount or rebate in its best price calculation, the United States could seek to force the manufacturer to recalculate its best price calculation including the relevant discount, to report the corrected best price information to the Secretary, and to make any additional payments necessitated by the recalculation. In that instance, regardless of whether the states joined the federal suit, the states would benefit as they would receive an additional rebate payment from the manufacturer if the United States prevailed at trial.

CONCLUSION

For the foregoing reasons, Montana and Nevada's state law best price claims are not inconsistent with the Medicaid rebate statute and therefore should not be preempted.

Respectfully submitted,

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